

Amendments to the Drawings:

The attached sheet of drawings includes changes to FIG. 1. This sheet, which includes only FIG. 1, replaces the replacement sheets of figures including FIG. 1 submitted August 16, 2004.

Attachment: Replacement Sheets

REMARKS/ARGUMENTS

The present application has been reviewed in light of the Final Office Action mailed October 25, 2004. Claims 16-19, 22-33 and 36-44 are pending in the application, claims 16, 22, 30, 37 and 44 having been amended herein. Reconsideration of the present application, as amended, is respectfully requested.

In view of the Examiner's earlier restriction requirement, Applicant reserves the right to present previously withdrawn claims 1-15 and 45-50 in a divisional application.

The amendment filed August 18, 2004, has been objected to under 35 U.S.C. §132 for introducing new matter into the disclosure, in particular, the material added at the end of the paragraph beginning at page 6, line 14 of the specification as well as the material in figure 1 of the drawings.

By the present amendment, the paragraph beginning at page 6, line 14 of the specification has been replaced with a revised paragraph. Accordingly, in view of the revision of the paragraph in question, it is respectfully submitted that the objection of the disclosure under 35 U.S.C. §132 should be withdrawn.

The drawings have been objected to for failing to show every feature of the invention specified in the claims, namely the locking structure defined in claims 23 and 37. Since claims 23 and 37 have been amended herein to remove the recitation of the locking structure, and since the specification has been amended at page 6 to remove the recitation of an exemplary locking structure, FIG. 1 has been amended to remove the illustration of the locking structure (e.g., tether

15) therefrom. Accordingly, in view of the amendments to the specification and to FIG. 1, and in view of the amendments of claims 23 and 37, the objection to the figures has been overcome.

Claim 22 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 has been amended herein in a manner which is believed to overcome the rejection of claim 22 under 35 U.S.C. §112, second paragraph.

Claims 16-19 and 22-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horzewski et al. (U.S. Patent 5,201,756) in view of Makower et al. (U.S. Patent 5,380,290). It is respectfully submitted that claim 16, as amended herein, is allowable over Horzewski '756 in view of Makower '290.

It is respectfully submitted that Horzewski '756, taken alone or in any proper combination with Makower '290, fails to teach or suggest amended independent claim 16.

Independent claim 16 presently recites a method for establishing vascular access, including the steps of, *inter alia*, positioning a radially expandable sleeve in direct contact with and over the guidewire and through the tissue tract with a distal end in the blood vessel and a proximal end outside the tissue tract, wherein the expandable sleeve is in a narrow diameter configuration; and inserting the dilator over the guidewire and into the radially expandable sleeve to radially expand the expandable sleeve to a larger diameter configuration to provide an access lumen to the blood vessel.

According to the present disclosure, with reference to FIGS. 2A-2E, with the guidewire GW in place in the tissue tract TT, as illustrated in Fig. 2B, the radially expandable sleeve 12 is

introduced over the guidewire GW so that its distal end 13 lies within the blood vessel BV, as shown in Fig. 2C. The dilator is then introduced over the guidewire GW so that the distal end of the dilator 14 causes radial expansion of the sleeve 12, as shown in Fig. 2D. (see page 7, lines 27-32).

Horzewski '756 discloses a sheath assembly consisting of a side arm sheath 90 and one or more dilators 150, 160. (see col. 11, lines 58-60). Typically, the sheath is prepared with the dilator 150 illustrated in FIG. 6B and this assembly is introduced over a guidewire within the confines of the vasculature. (see col. 12, lines 37-40) The sheath and dilator are designed such that the distal end of the sheath is proximal to the bulbous region 127 of said dilator. (see col. 12, lines 56-59).

Makower '290 discloses that the distal end of the dilator is inserted into the proximal end of the catheter or introducer sheath, and advanced so that the part of the dilator, having the small slit, can be seen protruding beyond the distal end of the introducer sheath. (see col. 9, lines 54-58). In use the sharp tip of the needle/dilator is inserted so that the tip of the needle and the tip of the dilator are simultaneously in the vessel. (see col. 10, lines 32-34). Next, the guidewire-stop is removed and discarded and the guidewire is advanced through the needle/dilator and then some distance into the vessel. (see col. 10, lines 48-50).

It is respectfully submitted that Horzewski '756, taken alone or in any proper combination with Makower '290, fails to teach, disclose or suggest, positioning a radially expandable sleeve in direct contact with and over the guidewire and through the tissue tract with a distal end in the blood vessel and a proximal end outside the tissue tract, wherein the expandable sleeve is in a narrow diameter configuration; and inserting the dilator over the

guidewire and into the radially expandable sleeve to radially expand the expansible sleeve to a larger diameter configuration to provide an access lumen to the blood vessel, as presently recited in claim 16.

It is therefore respectfully submitted that, in view of the amendments made to claim 16 herein, and in view of the arguments presented above, that claim 16 is allowable over Horzewski '756 in view of Makower '290.

Since claims 17-19 and 22-29 depend, directly or indirectly from claim 16 and contain all of the features of claim 16, for the reasons presented above regarding the patentability of claim 16, it is respectfully submitted that claims 17-19 and 22-29 are also patentable over Horzewski '756 in view of Makower '290.

Claims 30-33 and 36-44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horzewski '756 in view of Makower '290 as applied to claims 16-19 and 22-29 above, and further in view of Dubrul et al. (U.S. Patent 5,431,676). It is respectfully submitted that claims 30 and 44, as amended herein, are allowable over Horzewski '756 in view of Makower '290 and further in view of Dubrul '676.

It is respectfully submitted that Horzewski '756, taken alone or in proper combination with Makower '290 and/or Dubrul '676, fails to teach or suggest either of amended independent claims 30 and 44.

Independent claim 30 recites a method for establishing vascular access, including the steps of, *inter alia*, positioning a radially expandable sleeve directly over the guidewire and through the tissue tract with a distal end in the blood vessel and a proximal end outside the tissue

tract, wherein the expandable sleeve is in a narrow diameter configuration, wherein the radially expandable sleeve comprises a tubular braid formed of a mesh of non-elastic filaments which axially shorten the braid upon radial expansion thereof; introducing a dilator over the guidewire, and into and through the expandable sleeve to increase the diameter of the expandable sleeve to a larger diameter; and removing an inner dilator portion of the dilator from the expandable sleeve and leaving a sheath of the dilator interposed between the guidewire and the expandable sleeve, wherein the shaft causes the expandable sleeve to retain the larger diameter.

As discussed above, neither Horzewski '756 nor Makower '290 suggest, teach or disclose positioning a radially expandable sleeve directly over the guidewire, and introducing a dilator over the guidewire and into the expandable sleeve to increase the diameter of the expandable sleeve to a larger diameter, as called for in claim 30. Accordingly, for the reasons presented above regarding the patentability of claim 16 over Horzewski '756 and/or Makower '290, claim 30 is also allowable over Horzewski '756 and/or Makower '290.

The examiner relies on Dubrul '676 solely for the proposition of providing an expandable sleeve constructed as a tubular braid. However, Dubrul '676 fails to remedy the deficiencies of Horzewski '756 and/or Makower '290 in that Dubrul '676 fails to suggest, teach or disclose positioning a radially expandable sleeve directly over the guidewire, and introducing a dilator over the guidewire and into the expandable sleeve to increase the diameter of the expandable sleeve to a larger diameter, as called for in claim 30.

It is therefore respectfully submitted that, in view of the arguments presented above, that claim 30 is allowable over Horzewski '756, taken alone or in any proper combination with Makower '290, in view of Dubrul '676.

Since claims 31-33 and 36-43 depend, directly or indirectly from claim 30 and contain all of the features of claim 30, for the reasons presented above regarding the patentability of claim 30, it is respectfully submitted that claims 31-33 and 36-43 are also patentable over Horzewski '756, taken alone or in any proper combination with Makower '290, in view of Dubrul '676.

Independent claim 44 presently recites an improved method for establishing vascular access comprising, *inter alia*, introducing a radially expandable sleeve directly over the guidewire prior to introducing the dilator, and thereafter introducing the dilator over the guidewire and into the sleeve.

As discussed above with regard to the patentability of claim 30, it is respectfully submitted that Horzewski '756, taken alone or in any proper combination with Makower '290, in view of Dubrul '676, fails to suggest, teach or disclose introducing a radially expandable sleeve directly over the guidewire prior to introducing the dilator, and thereafter introducing the dilator over the guidewire and into the sleeve, as presently recited in claim 44.

Accordingly, in view of the amendments to claim 44 and in view of the arguments presented above, it is respectfully submitted that claim 44 is allowable over Horzewski '756, taken alone or in any proper combination with Makower '290, in view of Dubrul '676.

In view of the amendments made to the claims herein, and in view of the remarks/arguments presented above, it is respectfully submitted that each of the objections and rejections raised by the examiner in the present Office Action have been overcome.

It is respectfully submitted that none of the references of record, considered individually or in any proper combination, disclose or suggest the present invention as claimed.

Should the Examiner believe that a telephone interview may facilitate resolution of any outstanding issues, the Examiner is respectfully requested to telephone Applicants' undersigned attorney at the number indicated below.

In view of the foregoing amendments and remarks, reconsideration of the application and allowance of claims 16-19, 22-33 and 36-44 is earnestly solicited.

Respectfully submitted,

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